IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

BICHON et al

Atty. Ref.: 1201-97

Serial No. To be Assigned

Group:

Filed: December 3, 2003

Examiner:

For: GAS OR AIR FILLED POLYMERIC MICROBALLOONS USABLE AS SUSPENSIONS IN LIQUID CARRIERS FOR

ULTRASONIC ECHOGRAPHY

December 3, 2003

Assistant Commissioner for Patents Washington, DC 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. § 1.55 and in conformance with the procedures of 37 C.F.R. § 1.98, applicants hereby bring the following references to the attention of the examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. A copy of the patent, publication or other information listed on the modified PTO form 1449 will be found in the parent case Serial No. 08/910,152.

Please return to the undersigned a copy of the attached PTO-1449 with the examiner's initials in the left column [MPEP § 609] with the next communication. BICHON et al Serial No. To be Assigned

Respectfully submitted,
NIXON & VANDERHYE P.C.
By:
Arthur R. Crawford

Reg. No. 25,327

ARC:eaw 1100 North Glebe Road, 8th Floor Arlington, VA 22201-4714 Telephone: (703) 816-4000

Facsimile: (703) 816-4100

Based on Form PTO-1449 (3/90)	ATTY. DOCKET NO.	SERIAL NO.
LIST OF REFERENCES CITED BY APPLICANT Sheet 1 of 8	Error! Reference source not found97	TO BE ASSIGNED
(Use several sheets if necessary)		
	APPLICAN	NTS
	BICHON e	et al
	FILING DATE	GROUP
	December 3, 2003	

		U.S. PAT	ENT DOCUMENTS			
						FILING
EXAMINER INITIAL	DOCUMENT NUMBER	ISSUE DATE	NAME	CLASS	SUB- CLASS	DATE IF APPROPRIATE
	5,730,954	3/24/98	Albayrak et al.			
	4,935,246	6/1990	Ahrens			
	5,599,523	2/4/97	Beller			
	4,832,941	5/23/89	Berwing	ŀ		
	5,711,933	1/27/98	Bichon et al.			
	4,957,656	9/18/90	Cerny	l.		
	5,487,390	1/1996	Cohen et al	Ì		
	4,684,479	8/4/87	D'Arrigo			
	4,859,363	8/22/89	Davis	İ		
	3,615,972	10/26/71	Morehouse		<u> </u>	
	5,137,928	8/11/92	Erbel		<u> </u>	
	5,190,982	3/2//93	Erbel		<u> </u>	
····	5,205,287	4/27/93	Erbel			
	4,370,349	1/25/83	Evans			
	4,718,433	1/12/88	Feinstein			
	4,572,203	2/25/86	Feinstein			
	4,774,958	10/4/88	Feinstein	<u> </u>		
	5,049,322	9/17/91	Fessi	 		. , , .
	5,283,067	1/1/94	Geller	1		
	5,147,631	9/15/92	Glajch et al.		<u> </u>	
	5,364,612	11/15/94	Goldenberg		<u> </u>	
	5,089,181	2/18/92	Hauser			-
	4,466,442	8/21/84	Hilmann et al.	 		
	4,789,550	12/1988	Hommel et al			
	4,675,189	6/1987	Kent et al			
	5,529,766	6/25/96	Klaveness	<u> </u>		
	5,536,490	7/16/96	Klaveness			
	5,567,413	10/22/96	Klaveness			
- 	5,558,856	9/24/96	Klaveness et al.	-	 	
	4,569,844	1/1986	Jones			
 	3,650,831	N/A	Jungermann		1	
·	5,552,133	9/3/96	Lambert et al.	 	 	
	5,536,489	7/16/96	Lohrmann			
	5,716,597	2/10/98	Lohrmann et al.			
	4,927,623	5/22/90	Long	 	 	
	4,192,859	3/11/80	Mackaness, et al	1	 	
	4,027,007	5/3177	Messina	1	 .	
	5,601,085	2/11/97	Østensen	 	 	
	4,235,871	11/25/80	Papahadjopoulos, et al.	 	 	
	EXAMINER	11,25,00	1 - spaniasjoposios ; ot un	DATE CONS	IDERED	<u> </u>

Based	on Form PTO-1449		ATTY. DOCKE	ΓNO.	SERIAL NO.
(3/90)				·	
	LIST OF REFERENCES CITED BY		Error! Reference source	not found97	TO BE ASSIGNED
APPLICANT Sheet 2 of 8		Error. Reference source	not round57	TO BE ASSIGNED	
(Use	several sheets if necess	ary)			
				APPLICAN'	TS.
				BICHON et	al
			FILING DAT	r I	GROUP
			December 3, 2		GROUP
			December 3, 2	<u> </u>	· · · · · · · · · · · · · · · · · · ·
	5,409,688	4/25/95	Quay		
	5,393,524	2/28/95	Quay		
	4,442,843	4/17/84	Rasor		
	4,657,756	4/14/87	Rasor		
	4,681,119	7/21/87	Rasor		
	5,141,738	8/25/92	Rasor		
	5,425,366	6/20/95	Reinhardt		
	5,501,863	3/26/96	Rössling et al.		
	5,593,687	1/14/97	Rössling et al.		•
	4,544,545	10/1/85	Ryan	<u> </u>	
	4,900,540	2/13/90	Ryan et al.		
	4,224,179	9/23/80	Schneider		
	4,229,360	10/21/80	Schneider		
	5,271,928	12/21/93	Schneider		
ļ	5,312,615	5//17/94	Schneider		
	5,380,519	1/10/95	Schneider		
	5,413,774	5/9/95	Schneider		
	5,445,813	8/29/95	Schneider		
	5,531,980	7/2/96	Schneider		
	5,643,553	7/1/97 8/19/97	Schneider Schneider		
	5,658,551 5,567,414	10/22/96	Schneider		
	5,639,443	6/17/97	Schutt et al.		
	5,195,520	3/23/93	Schlief Schlief		
	5,380,411	1/10/95	Schlief		· · · · · · · · · · · · · · · · · · ·
	5,670,135	9/23/97	Schroder		-
 	3,900,420	8/19/75	Sebba	+	
	3,968,203	7/6/76	Spitzer		
	5,425,366	6/20/95	Stein		
	4,089,800	5/1978	Temple		
	4,265,251	5/5/81	Tickner		
	4,316,391	2/23/82	Tickner		
	4,276,885	7/7/81	Tickner et al.		
	5,088,499	2/18/92	Unger		
	5,123,414	6/23/92	Unger		
	5,149,319	9/22/92	Unger		
	5,527,521	6/1996	Unger		
	5,209,720	5/11/93	Unger		
	5,228,446	7/20/93	Unger		
	5,874,062	2/23/99	Unger		
	5,776,429	7/7/98	Unger et al.		
	5,776,496	7/1998	Violante et al		
	5,352,436	10/4/94	Wheatley		
	4,844,882	7/4/89	Widder et al.		

797746

•*	Based on Form PTO-1449 (3/90)	ATTY. DOCKET NO.	SERIAL NO.
	LIST OF REFERENCES CITED BY APPLICANT Sheet 3 of 8	Error! Reference source not found97	TO BE ASSIGNED
	(Use several sheets if necessary)		
		APPLICAN BICHON e	·
		FILING DATE December 3, 2003	GROUP
	5,556,610 9/17/96	Yan et al.	T

Based on Form PTO-1449 (3/90)	ATTY. DOCKET NO.	SERIAL NO.
LIST OF REFERENCES CITED BY APPLICANT Sheet 4 of 8	Error! Reference source not found97	TO BE ASSIGNED
(Use several sheets if necessary)		
	APPLICAN	VTS
	BICHON e	t al
	FILING DATE	GROUP
	December 3, 2003	

·	FOREIGN PA	TENT DOCUMENTS				-
DOCUMENT NUMBER	PUBLIC- ATION DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLA	ATION
					YES	NO
ZA 910961 (Albayrak)		South Africa				
EP 0 274 961	7/1988	EP				
EP A 458 745 (Bichon et al.)	11/27/91	EP				
EP 359 246 A2 (Cerny)	3/21/90	EP				
EP 359 246 A3 (Cerny)	3/21/90	EP				
GB 1,044,680 (Dow Chemical)	10/5/66	Great Britain				
WO 84/02838 (Feinstein)	8/2/84	PCT				
WO 89/05160 (PCT DE 988/00751) (Fritzsch)	6/15/89	PCT			Х	
WO 92/05806 (Giddey)	4/16/92	PCT				
WO 92/19273 (EP 0 583 390) (Goldenberg)	11/12/92	PCT				
DE A 41 27 442 (Gross)	2/18/93	Germany			X	
CA 1239092 (Hilmann)	7/12/88	Caṇada				
CA 1232837 (Hilmann)	2/16/88	Canada				
WO 91/12823 (Illum et al.)	9/5/91	PCT				
WO A 92/17212 (EP 0 576 519) (Klaveness)	10/15/92	PCT				
WO 92/17213 (EP 0 576 521) (Klaveness)	10/15/92	PCT			_	
WO 92/21382 (EP 0 586 524) (Klaveness)	12/10/92	PCT				

EXAMINER	DATE CONSIDERED
* EXAMINER: Initial if reference considered, whether or not	-
citation if not in conformance and not considered. Include copy	of this form with next communication to applicant.

or I	Based on Form PTO-1449 (3/90)		ATTY. DOCKE	T NO.	S	ERIAL NO.
	IST OF REFERENCES CITE APPLICANT Sheet 5 of 8	D BY	Error! Reference source	not found97	TO I	BE ASSIGNED
	(Use several sheets if necessar	ıry)				
		• /		APPLICANT BICHON et a		
			FILING DAT December 3, 2			GROUP
	CA 2077383 (EP 0535387)	3/4/93	Canada			
	(Krone)	44.400	DOM:			
	WO 93/5819 (EP 0 605 477) (Quay)	4/1/93	PCT			
	WO 94/16739 (Quay)	8/4/94	PCT	·		
	WO 88/7365 (Ranney)	10/6/88	PCT			
	EP A 131 540 (Rasor & Tickner)	1/16/85	EP			X
	GB 213 5647 (Ridgway)	9/5/84	Great Britain			
	WO 91/15244 (Schneider et al)	10/17/91	PCT		١	
	EP A 554 213 (Schneider)	4/8/93	EP			:
	WO-A-85/02772 (Schroder)	7/4/85	PCT			
	NZ 253115 (Stein)	1/26/96	New Zealand			
	WO 92/18164 (Sutton)	10/29/92	PCT			
	WO-A-80/2365 (Tickner et al.)	11/13/80	PCT			
	WO 91/09629 (Unger)	7/11/91	PCT			
	WO 92/22247 (Unger)	12/23/92	PCT			
	WO 92/17514 (Unger)	10/15/92	PCT			
	WO 93/06869 (Vanderipe)	4/15/93	PCT			
	EP A 324 938 (Widder et al.)	7/26/89	EP			
	EP 0 123 235	4/1984	EP			<u> </u>

EXAMINER	DATE CONSIDERED
	citation is in conformance with MPEP 609. Draw line through
citation if not in conformance and not considered. Include copy	of this form with next communication to applicant.

Based on Form PTO-1449 (3/90)	ATTY. DOCKET NO.	SERIAL NO.
LIST OF REFERENCES CITED BY APPLICANT Sheet 6 of 8	Error! Reference source not found97	TO BE ASSIGNED
(Use several sheets if necessary)		
	APPLICAN BICHON e	·
	FILING DATE December 3, 2003	GROUP

	OTHER PRIOR ART (Including	ng Author, Title, Date, Pertinent Pages, Etc.)
	Biochemistry/Ed. Stryer - 2 Ed., San Francisc	
	Concise Encyclopedia Of Polymer Sci. and E	
		eering, 2nd ed., <u>10</u> , p. 95, Wiley & Sons, 1987)
	Encyclopedia of Polymer Science and Engine	
 		lications," <u>DuPont Technical Bulletin</u> , pp. 1-11 (1964)
	""Freon" DuPont Technical Bulletin, pp. 1-1	
	Gas Encyclopedia, Elsevier Publishier (1976)	_ · · · · · · · · · · · · · · · · · · ·
	Handbook of Pharmaceutical Excipients: Am	
		
	"Lecithin" in Rompp Chemie Kexikon, p. 24	
		tionary, 4th Ed., N.Y., Mcgraw-Hill,, p. 749 (1979)
		Dictionary, 26 Ed., Philadelphia, Saunders, p. 721 (1981)
		Publ. Comp., 295-298: 736; 1242-44 (1975)
	Barnhart et al., Invest. Radiol, 25, 162-164 (1	
		nce, 73, pp. 1721-1724 (1984) "Characterization of Drug
	Loaded Polydilactide Microspheres"	
l		pr. 1990, pp. 1792-1797, "Ultrasonic characterization of
	Albunex [®] "	
	Bleeker, et al., 1990 J. Ultrasound Med., 9:46	61-471, (1999), "On the Application of Ultrasonic Contrast
	Agents"	•
	Bommer et al., Abstract of the 54 Scient. Sess	sions, Circulation <u>64</u> , - 203, Abst. 770 (1981)
İ		1984) "Stability of Liposomes on Storage"
		ers Symp., pp. 88-93 (1986) "Freezing and Freeze Drying of
	Liposomes"	
	<u> </u>	opedia of Biochemistry, Berlin, pp. 348-49 (1983)
		2, pp. 95-103, "Absorption and scatter of encapsulated gas
	filled microspheres"	
		, pp. 324-330, "Principles and recent developments in
	ultrasound"	, pp. 32 · 330, 11 merpios una recent de veropinente in
		, No. 3 (1983), "Scattering of focused ultrasound by spherical
	microparticles"	, 110. 5 (1705), beautiful of focused diffusioning by spherical
		. 11, pp. 1505-1509, Nov. 1950, "On the Stability of Gas
	Bubbles in Liquid-Gas Solutions"	. 11, pp. 1303-1307, 1101. 1730, On the Stability of Gas
		316-24, "Safety and Efficacy of a New Transpulmonary
		onograph Circulation, Part II, Vol. 72, No. 4, Oct. 1985,
	Abstracts of the 58 th Scientific Ses.	<u>5110graph Chediation</u> , 1 art 11, voi. 1/2, 140. 4, Oct. 1983,
	Fainctain et al. Am. L of Physiologic Imagis	ng, 1:12-18 (1986), "Myocardial Contrast Echocardiography
	", Ain. J. of Physiologic Imagn	ng, 1.12-18 (1980), Wryocardiai Contrast Echocardiography
	Fainstein Laftha Amon Call of Condial 9.0	251-253 (1986) "Myocardial Perfusion Imaging"
		nterfacial polymer deposition," Int. J. Pharm., 1989, Vol.
	55, No. 1, pp. R1-R4	(1056) 0.47
	Fieser and Fieser, Organic Chemistry, 3rd ed	
ı		91) 242-245, "Farbkodierte Duplexsonographic und
	Ultraschallkontrast mittel" EXAMINER	DATE CONSIDERED

Based on Form PTO-1449	ATTY. DOCKET NO.	SERIAL NO.
(3/90) LIST OF REFERENCES CITED BY APPLICANT Sheet 7 of 8	Error! Reference source not found97	TO BE ASSIGNED
(Use several sheets if necessary)		
	APPLICAN	NTS
	BICHON e	t al
	FILING DATE	GROUP
	December 3, 2003	

Ganguly et al., "Structure of hollow polystyrene microspheres" J. Microencapsulation, Vol. 6, No. 2, 193-198 (1989)
Gardner, et al., (1988), "A Survey of Intraocular Gas Use in North America," Arch. Ophthalmol., 106:1188-1189
Goldberg et al., Radiology, 177, pp. 713-7 (1990) "Hepatic Tumors"
Gregoriadis, Gregory, <u>Liposome Technology</u> , Volume I, "Preparation of Liposomes", CRC Press., pp. 172-77.
Helzel, Fortschr. Rontgenste, 140, pp. 337-340 (1984) "Erste Erfahrurgen"
Henry-Michelland et al., Colloids and Surfaces, 14, pp. 269-276 (1985) "Lyophilization and Rehydration of Liposomes"
Jacobs, "Intraocular gas measurement using A-scan ultrasound," <u>Current Eye Research</u> , Vol. 5, No. 8, 1986, pp. 575-578
Keller et al, Circulation Res, 65, 458-467 (1989) "The Behavior of Sonicated Albumin"
Krause et al., <u>International Journal of Pharmaceutics</u> ., <u>27</u> , pp. 145-155 (1985) "Polylactic acid nanoparticle"
Levene et al, J. Acoust. Soc. Am., 87 (Suppl) 69 (1990) "Characterization of Albunex"
Lincoff, et al., "Intravitreal Longevity of Three Perfluorocarbon Cases, Arch. Ophthalmology, 98:1610-1611 (1980)
Lincoff, et al., "Intravitreal Expansion of Perfluorocarbon Bubbles," <u>Arch. Ophthalmology</u> , 98:1646 (1980)
Lincoff, et al., "The Perfluorocarbon Gases in the Treatment of Retinal Detachment," Ophthalmology, 90(5):546-551 (1983)
Lincoff, et al., "Perfluoro-n-butane: A Gas for Maximum Duration Retinal Tamponade," <u>Arch.</u> <u>Ophthalmology</u> , 101:460-463 (1983)
K. Makino, "Preparation and in vivo degradation properties," Chem. Pharm. Bull., (1985), Vol. 33, No. 3, pp. 1195-1201
Mattrey et al., Radiology, 148, pp. 759-762 (Dec. 1982) "UHM Sound; Perfluoroctylbr omide"
Chem Abs., Vol. 102. No. 3, 21 (Jan. 1985), Maynard et al., "Ultrasonic absorption by liposomes"
Meltzer, et al., <u>Ultrasound in Med. & Biol.</u> , Vol. 7, No. 4, pp. 377-384, 1981, "Transmission of Ultrasonic Contrast Through the Lungs"
Miller et al., J. Amer. Soc. Anesthesiol., 36 339-351 (1971) "Physicochemical Approaches"
Möhwald, Annu. Rev. Phys. Chem., 41, 441-76 (1990) "Phospholipid and Phospholipid-Protein Monolayers At The Air/Water Interface"
Murrell et al, "Properties of liquids and solutions", Wiley, p. 276 (1982)
Nomura, et al., "US Contrast Enhancement of Hepatic Tumor with Helium Gas Microbubbles: A Preliminary Report," Jpn. J. Med. Ultrasonics, Vol. 18, No. 5, 1991, pp. 444-450
O'Hara et al, Journal of Membrane Science, 23 (1985) 1-9, "Preparation of ethylcellulose"
Ohta, et al., <u>Jpn. J. Med. Ultrasonics</u> , Vol. 18, No. 4 (1991), "Effect of the Contrast Agent and the Agitation Met."
Ophir, et al., <u>Ultrasound in Med. & Biol.</u> , Vol 15, No. 4, pp. 319-333, 1989, "Contrast Agents in Diagnostic Ultras."
Ostro in Spektrum d. Wiss, 94-95, 98 (Marz 1987). "Liposomen"
Özer et al., Acta Pharm. Tech. 34, pp. 129-139 (1988) "Influence of Freezing and Freeze Drying on Stability of Liposome"

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through		EXAMINER	DATE CONSIDERED
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

Based on Form PTO-1449 (3/90)	ATTY. DOCKET NO.	SERIAL NO.
LIST OF REFERENCES CITED BY APPLICANT Sheet 8 of 8	Error! Reference source not found97	TO BE ASSIGNED
(Use several sheets if necessary)		
	APPLICANTS BICHON et al	
	FILING DATE December 3, 2003	GROUP

Park, et al., <u>Journal of Chemical And Engineering Data</u> , Vol. 27, No. 3 (1982), "Solubility of Gases in Liquids. 14. Bunsen Coefficients for Several Fluorine-Containing Gases (Freons) Dissolved in Water at 298.15K"
Peters et al., Am. J. Ophthalmol. 100 pp. 831-839 (1985) "The non expansive, equilibrated concentration
of perfuoropropane in the eye"
Puisieux et al., Bull. Soc. Pharm. Bordeaux, 123, pp. 111-126 (1984) "Les Liposomes"
Rompp Lex. Chemie. 8 Aufl. Stuttgart: Franckh; Bd. Z: Cm-G, (1981): Bd 3; H-L, (1983); Bd 4, M-Pk (1985) "Porositat"
Rompps Chemie Lexikon, "Phospholipide"
Schlief, Current Opinion in Radiology, 1993, 3:198-207, "Ultrasound Contrast Agents"
Schneider, et al., Investigative Radiol., <u>26(1)</u> , pp. S190-91 (1991) "A New Ultrasound Contrast Agent Based on Biodegradable Polymers Microballoon"
Schneider, et al., Investigative Radiol., <u>29(2)</u> , pp. S149-51 (1991) "The Use of Polymers Microballoons as Ultrasound Contrast Agent"
Swanson, pp. 682-687, "Chapter 22: Enhancement Agents for Ultrasound: Fundamentals," Pharmaceuticals In Medical Imaging, (1990)
Szoka et al, PNAS 75, pp. 4194-4198 (Sept. 1978) "Procedure for preparation of Liposomes"
Tomlinson, Int. J. Pharm. Tech. & Prod. Mfr., 4, pp. 49-57 (1983) "Microsphere Delivery Systems"
Ulmius et al, Biochem., 21, p. 1553 (1982) "Molecular organization"
K. Uno, et al., "A new method of preparing monocored," J. Microencapsulation, 1984, Vol. 1, No. 1, pp. 3-8
Violante, et al., <u>Investigative Radiology</u> , Vol. 26, Nov. Supp 1991, "Particle-Stabilized Bubbles for Enhanced Organ Ultrasound Imaging"
Voigt et al., "Lzithine" in Lehrb. d. pharm. Tech. i, uberarb. Aufl Weinheim; VCH, p. 367 (1979)
Wheatley et al, Biomaterials 11, pp. 713-17 (1990) "Contrast agents for diagnostic ultrasound"
Widder, et al. AJR:147, Aug. 1986, "Microbubbles as Contrast Agent for Neurosonography and Ultrasound"
Fiedler, Lexikon der Hiffstoffe, 4, Auflage, 1182-85
Zhang, et al., J. East China Inst. Chem. Tech., 12(3) 343-345 (1986) "A Study on the Solubilities of F22 and C2F4 in Aqueous Solutions of HCl and NaCl"
Zeghlouol et al, <u>Journal de Chimie Physique</u> , 83; 665-671 (1986) "NMR And Microcalorimetry Study Of The Solubility Of Certain Halons And Their Interaction with Human Serum Albumin"
Ohara et al Preparation of Ethylcellulose-polystyrene Composite Microcapsules of 2-phase Structure and
Permeability of the Microcapsule Membranes Toward Phenobarbital", Vol. 80, Acc No. 8535072, Abstract
No. 25064 & Inst. Colloid Interface Sci., Tokyo, 162
Schering AB "Ultra-Sound Contrast Agent esp. for e.g. Heart, Veins - Comprises Microparticles of a Sugar and Gas Bubbles in a Liquid carrier", Acc No. 85-020020/04, Abs No. 008371
Finch (1985) Polymers for Microcapsule Walls Chem. and Industry pp. 752-756.
 1 VI VIII VIII VIII VIII VIII VIII VIII

EXAMINER	DATE CONSIDERED
	<u> </u>
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through	
citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	